Exhibit L

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CAUSE NO. 2012-CI-18690

JENNIFER RAMIREZ F/K/A JENNIFER GALINDO,	)	IN THE DISTRICT COURT
Plaintiff,	)	
vs.	)	438th JUDICIAL DISTRICT
CESAR REYES, JOHNSON & JOHNSON, INC., AND ETHICON, INC.,	)	
Defendants.	)	BEXAR COUNTY, TEXAS

VOLUME II

- - -

MARCH 31, 2016

- - -

Videotaped deposition of PEGGY PENCE, Ph.D., Volume II, held in the offices of Lopez McHugh, LLP, 100 Bayview Circle, Suite 5600, Newport Beach, California, commencing at 10:16 A.M., on the above date before Pamela Cotten, CSR, RDR, Certified Realtime Reporter, Certificate No. 4497.

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ALSO PRESENT:

JOHN SISSON, Videographer

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Witness: PEGGY PENCE, PhD (Volume II)

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NEWPORT BEACH, CALIFORNIA - THURSDAY, MARCH 31, 2016
10:16 A.M.

VIDEO OPERATOR SISSON: Good morning. We are now on the record. My name is John Sisson. I'm the videographer for Golkow Technologies.

Today is March 31, 2016. It is now 10:16 in the morning.

This video deposition is being held in Newport Beach, California, in the matter of Ramirez versus Ethicon, Incorporated, et al., for District Court, 438th Judicial District, Bexar County, Texas. Today we are taking Volume 2 in the deposition of Peggy Pence.

Counsel, will you please now identify yourselves for the record.

MR. GOSS: Tim Goss and Yvette Diaz for plaintiff.

VIDEO OPERATOR SISSON: On the phone?

MR. LEWIS: Brian Lewis for Ethicon and Johnson & Johnson.

MS. VERBEEK: Carol Verbeek for Dr. Cesar Reyes.

VIDEO OPERATOR SISSON: Thanks very much.

Will our court reporter please now -- reswear the witness. By the way, our court reporter today is Pam Cotten, my error.

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PEGGY PENCE, PhD, RAC, FRAPS,
called as a witness, and having been first duly sworn by the Certified Shorthand Reporter, was examined and testified as follows:

MR. GOSS: We are here for the continuation of Dr. Pence's deposition, but before we do that I understand that Ethicon's lawyer, Brian Lewis, wants to make a statement for the record.

MR. LEWIS: Yes. This is Brian Lewis. I'm an attorney for Ethicon and Johnson & Johnson. I'm with the law firm of Davis, Cedillo & Mendoza in San Antonio, Texas. I just want to note for the record that by our appearance here today in the continuation of Dr. Pence's second deposition, we are not waiving the objections made by Ethicon's counsel, Ms. Sutherland, during the initial deposition as to the continuation of this deposition, the nature of the deposition and trial deposition, and also the notice for the follow-up destination scheduled for today. We are also not waiving any of the objections and arguments that are also set forth in the motion that we filed on the 29th of March for a protective order and for a motion to compel additional time to depose plaintiff's expert. That motion is set for hearing

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tomorrow in the presiding court.

With that, we will continue to proceed with this deposition.

MR. GOSS: Okay. Obviously, that's all for discussion tomorrow, I guess.

EXAMINATION

BY MR. GOSS:

Q Okay. Good morning, Dr. Pence.

A Good morning, Mr. Goss.

Q And you understand this is the continuation of your deposition testimony?

A Yes, I do.

Q Okay. I want to -- and just for the record, we are waiting for some of the exhibits -- well, all the exhibits that were used in your deposition last week. They didn't make it over by 10:00 from the court reporter. I understand the court reporter firm is going to try to get them here by 10:30. It is now 10:15 or -16 or so. So I'm going to start a little -- a place that might be a little awkward in my outline, then we will pick back up to where we stopped last time. Okay?

A Sounds fine.

VIDEO OPERATOR SISSON: If you could pause for a

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second. 10:19, we are off the record.

(Off-the-record discussion.)

VIDEO OPERATOR SISSON: At 10:20, we are back on the record.

MR. GOSS: Let me also add that, out of fairness, what I am trying to do this morning is I have forwarded to -- as soon as I got the email for the counsel that would be defending the depositions for the defendants, I have forwarded a group of slides and some other things that I wanted to make sure that they had before we got started so as to not be at a disadvantage.

I have also informed counsel that if during the deposition there is something that I'm using that you need to see, I will endeavor to get it emailed to you as quickly as possible. I think I can do it fairly quickly because I think we have got most of the exhibits handy on -- I don't know a lot about computers, but on a hard drive or whatever it is called.

Okay. With that, I'm going to go forward. I assume, as I understand it, the lawyers on the phone, you have received my first group of documents that I've emailed to you; is that right?

MR. LEWIS: That's correct.

MR. GOSS: Okay. Carol?

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MS. DIAZ: Oh, sorry. You were on mute. That's correct.
MR. GOSS: Okay. All right. With that, I'll proceed.
BY MR. GOSS:
Q Dr. Pence, I would like to talk to you a little bit about heavyweight mesh. Okay?
A Okay.
Q You understand what I'm talking about when I say "heavyweight mesh"?
A Yes, I do.
Q In your investigation of Ethicon, did you review any testimony or internal documents regarding heavyweight mesh versus lightweight mesh?
A Yes, I did.
Q Did you review any testimony from Ethicon as to whether -- the mesh in the Prolene mesh, or TVT-O, that Jennifer Ramirez got, whether that mesh was heavyweight or lightweight?
A Yes, I did.
Q And what did you review, what testimony?
A I reviewed the testimony, for example, of Dr. Joerg Holste, who is in charge of preclinical development, has been with the company for over 30 years, and which he testified that the Prolene mesh is

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heavyweight mesh.
(The documents referenced below were marked Deposition Exhibits 47 and 48 for identification and are appended hereto.)
BY MR. GOSS:
Q Okay. I'm going to hand you what's been marked as your Exhibits 47 and 48. I actually probably did this backwards, now that I look at it, but is Exhibit 48 a transcript -- it appears to be a transcript dated July 29th, 2013, given in the MDL in West Virginia for the videotaped deposition of Dr. Holste.
Is that a transcript that you reviewed in your investigation in this case?
A Yes, it is.
Q Is that a transcript that you relied on in whole or in part for some of your opinions in this case?
A Yes.
Q Okay. And I'm going to ask you the same questions regarding Exhibit 47, which on its face reflects that it is Volume II of a deposition transcript given in the MDL for Dr. Holste on July 30th, 2013.

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Is that a transcript that you reviewed in your investigation in this case?
A Yes, it is.
Q And did the testimony in that transcript form the basis in whole or in part in any of your opinions in this case?
A Yes.
Q Okay. And to back up a little bit, is Dr. Holste the one whose testimony you said supports your understanding that it was heavyweight mesh?
A Yes.
Q In that regard, I'm going to refer you to the July 29th transcript at page 40, lines 12 through 15, and ask that you read those lines, 12 through 15, question and answer.
"Question: And Prolene, old-construction mesh at 100 to 110 grams per meter squared is considered a heavyweight mesh; correct?
"Answer: Yes."
Q And is that the testimony you relied upon for support of your opinion it's heavyweight mesh?
A Yes.
Q Do you know whether or not the Prolene old-construction mesh that's referenced in the

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testimony that you just read is the same mesh that is used in the TVT-O?
A Yes.
Q Is it?
A Yes, it is.
Q In your investigation, did you see there any discussion as to any of the risks that may be created by heavyweight mesh?
A Yes.
Q And did you review any testimony in that regard?
A Yes.
Q And whose testimony did you review?
A I read, for example, Dr. Holste's testimony. He did testify about that.
Q Okay. I would like to refer you to -- I've got an excerpt here for you -- refer you to pages 51 through 53 of the July 29th testimony. Is any of that testimony anything that you relied upon in forming your opinions in this case?
A Yes, it is.
Q And on page 51 at line 25, it begins with a question.
"One of the reasons" --
"Question: One of the reasons that

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Ethicon developed a lighter-weight large-pore mesh was so that less foreign material would be left behind in the tissue; correct?
"Answer: That is correct, yes,
"Question: Because the more foreign material that's left in the tissue, the greater the foreign-body reaction; correct?"
Some objections
"Answer: That is correct, yes.
"And if more foreign body that's in the body that creates a greater foreign-body reaction also can create a greater inflammatory reaction; correct?
"Answer: Yes.
"And if you have more foreign material causing a greater inflammatory reaction, it can cause complications in patients; correct?
"That can be assumed, yes.
"Question: One of the problems that a greater inflammatory reaction can cause in the human tissue to a foreign body like a polypropylene mesh implant

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is if there can be more contraction, sometimes known as mesh shrinkage; correct?
"Answer: Yes."
Did I read that correctly?
A Yes, you did.
Q And what did you rely upon, with respect to that testimony, for your opinion, if any?
A With regard to the fact that the heavier-weight mesh does result in a greater foreign-body reaction, greater inflammatory reaction, and that greater inflammatory reaction, as is noted in the testimony -- and this is also reported in the literature and other places as well, documentation and testimony that I reviewed -- that additional greater inflammatory reaction can result in more -- more of a -- of a contraction. The tissue around the mesh can compress the mesh and cause a contraction. That can cause pain. It could cause other types of complications as well.
Q Does the 2010 IFU reflect whether the mesh is heavyweight or lightweight?
A No, it does not.
Q And would the standard in the industry be for it to reflect heavyweight or lightweight?

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A If it impacts safety and performance, yes, that would be appropriate.
Q Based upon Dr. Holste's testimony, would it impact safety or performance?
A Yes.
Q Do you know -- first of all, did you review in your investigation of Ethicon's files any documents that reflected whether or not Ethicon had lighter-weight meshes than Prolene mesh prior to 2010?
A Yes.
Q And what did your investigation determine?
A Yes, the company did have other meshes that were lighter weight.
Q What were those -- some of those other meshes?
A ULTRAPRO, Vypro, for example.
Q Okay. Were any of those meshes that were lighter-weight meshes being used?
A In other products, yes.
Q Did you see anything in your investigation, any documents or testimony in your investigation as to why -- as to why a lighter-weight mesh could not have been used in the TVT-O?
A No.
MR. LEWIS: Objection. Form.
THE WITNESS: The company would have obviously had

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to do the appropriate development work, but, no, they had the mesh available and could have done the development work.
BY MR. GOSS:
Q Did you see whether or not the company did any development work or clinical testing of any lighter-weight meshes for the TVT-O?
A No.
Q Okay. Would a reasonable and prudent manufacturer have done those tests?
A Yes.
Q Would those types of tests be mandated by the Global Harmonization Task Force guidelines, for example, the clinical evaluation document that we have looked at?
A In terms of providing a safer alternative, if there is a safer alternative available, it would be appropriate for a company to -- if there is a problem with safety and performance related to the material and the design of the product, it would be appropriate to implement an improved design, yes --
Q And I believe we looked at --
MR. LEWIS: Objection. Nonresponsive.
BY MR. GOSS:
Q I believe we looked at a document early on --

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the first day of your deposition, from the Global Harmonization Task Force entitled Essential Principles of Safety in Performance of Medical Devices.

Do you recall that?

A Yes, I do.

Q Was there anything in that guideline -- which I understand you said were standards in the industry; is that correct?

A Right.

Q Is there anything in that guideline that would require a manufacturer to eliminate risk as reasonably practical?

A Yes. One is the global standard for medical device development requires that safety and performance information related to a product is fed back into the risk analysis so that there is -- that the benefit -- that there's always a favorable benefit-to-risk ratio and that any risks are acceptable, and if one has to mitigate risk when one learns of safety issues. And the discussion that we are having, one of the ways to mitigate risk with TVT-O would have been to implement a lighter-weight product, lighter-weight mesh.

MR. LEWIS: Objection. Nonresponsive.

BY MR. GOSS:

Q I want to just reference you back to the

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Global Harmonization Task Force document, just so we can reorient ourselves. Can you explain what the Global Harmonization --

A Certainly.

Q -- Task Force various guidelines are, what that is and what the various guidelines are?

A Yes. The Global Harmonization Task Force, often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It had five founding members, one of which was the United States as well as Europe, Japan, Australia, and Canada, if I recall correctly as I sit here today. And the purpose of that organization was to bring both industry representatives as well as regulators from these various countries, and some additional bodies and entities involved in medical device development later entered the group as well.

The idea was to develop a global model for the development of medical devices worldwide, essentially a global standard to enhance patient safety and bringing innovative new medical devices to market efficiently.

(The document referenced below was marked Deposition Exhibit 49 for identification and is appended hereto.)

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BY MR. GOSS:

Q Okay. I'm going to -- as I mentioned before we started the deposition, the exhibits aren't here yet from your prior deposition, so I'm going to mark another one of the Global Harmonization Task Force documents that we used last deposition as one entitled Essential Principles of Safety and Performance of Medical Devices.

Do you remember that one?

A Yes.

Q Dated May 20th, 2005, and I would like -- I'm marking this as Exhibit 49. I'll hand it to you.

I'll represent to you that I have highlighted on page 8 and 9 for future use as a potential slide some language I want to talk with you about.

But is Exhibit 49 the document -- one of the documents that you have discussed in your deposition last week?

A Yes, it is. It is one of the guidance documents for GHTF, and it is through a number of guidance documents that GHTF implemented or developed that global model for medical device development that I was mentioning.

Q Okay. And if you would go to page -- is it 8?

A Eight.

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Q Go to page 8, section 5.2 of page 8, where it picks up with, "The manufacturer should apply the following principles in the priority order listed," and it says, the first bullet point on page 8:

"Identify known or foreseeable hazards and estimate the associated risk arising from the intended use of foreseeable misuse."

The next bullet point:

"Eliminate risk as far as reasonably practical through inherently safe design and manufacture."

Third bullet point:

"Reduce as far as reasonably practical the remaining risk by taking adequate protection measures, including alarms."

And the last point:

"Inform users of any residual risk."

Did I read that right?

A Yes, you did.

Q Okay. Do any of these apply to your testimony relating to heavyweight and lightweight meshes?

A Yes, they do.

Q Explain, please.

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A For example, "Identify known or foreseeable hazards and estimate the associated risk arising from the intended use." In terms of the heavyweight mesh and the fact that, as Dr. Holste testified and as we were just discussing, that the greater -- that the heavyweight mesh causes a greater foreign-body reaction, a greater inflammatory reaction, which can cause greater contraction and shrinkage which can have complications associated with it, that is relevant to that issue with heavyweight mesh.

Secondly, "Eliminating risk as far as reasonably practical through inherently safe design and manufacture." That goes back to what I was saying a short while ago, that knowing that lighter-weight mesh can reduce the foreign-body -- has the potential to reduce the foreign-body reaction and inflammatory reaction, therefore, may cause reduced complications. That would mean that that would be a safer design. So that -- that point goes to --

Q Okay.

A -- to that.

Q You are referencing Exhibit 49. And is it your position these are the written standards in the industry, some of them?

A Yes. This is the -- this is one of the

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guidance documents, a very key document, Essential Principles of Safety and Performance, that is part of the global model that has been developed for medical devices through the work of the Global Harmonization Task Force.

Q Okay. Let's move off that subject. I think that we marked the 2010 IFU last time and, again, the exhibits aren't here -- that's them?

MS. DIAZ: Uh-huh.

MR. GOSS: I'm told that the exhibits just arrived. Let me see those. So we now have the exhibits. I see. All right.

So, Ms. Court Reporter, I know that you can't type and talk at the same time, so what I've got here is I've got a set of exhibits that go through 46?

THE REPORTER: Yes.

MR. GOSS: And we just picked up with 47. Okay. All right. For everybody on the phone, we now have the stack of exhibits, and you all should have copies of those that were provided during the deposition last week.

BY MR. GOSS:

Q So, Dr. Pence, I'm going to hand to you -- I'm going to hand you what was marked in your deposition last week, the 2010 IFU for the TVT-O.

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Do you recognize that document?

A Yes, I do. Thank you.

Q And there was a little bit of discussion about that last week, as I recall; is that right?

A Yes. To the best of my recollection also, yes.

Q I'm going to mark a -- what was marked as Exhibit 10 was the deposition exhibit for Dr. -- when it was used with Dr. Reyes and it only has the English version of it. Is that right?

A Yes.

MR. GOSS: So unless someone objects, just so that we have a complete IFU in the record, I'm going to mark the complete IFU as Exhibit 10A.

And just for those folks on the phone, all it has done -- all it adds is all the different languages. So 10, which we used last week, is the English -- just up through the English, and I'm going to mark 10A just so we have a complete record.

(The document referenced above was marked Deposition Exhibit 10A for identification and is appended hereto.)

BY MR. GOSS:

Q Dr. Pence, is Exhibit 10 simply the English version taken out of the whole 10A?

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A Yes.

Q Okay. All right.

All right. Now, when I retained you in this case, was one of the things that I asked you to look at the IFU?

A Yes.

Q And I asked you to determine whether or not it was adequate or inadequate?

A That is correct.

Q Did you ever endeavor to do so?

A I did.

Q All right. Are there professional standards that set forth what should go into an IFU?

A Yes, there are.

Q And are you familiar with those standards?

A Yes, I am.

Q Just to back up a little bit, explain to the jury what the IFU is.

A The IFU stands for Instructions For Use. It is the cornerstone of risk management because it is the primary communication between the manufacturer and the user of the device, in this case a surgeon. It provides information on the purpose of the device, what it is to be used for, how -- the patient population, the types of patients in which it is to be used, how it

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is to be used, the instructions for its use, and, very importantly, safety and risk information.
Q Okay.
A If I might add, the key purpose, it should include all information necessary for the safe and effective use of the device.
Q Is there any debate about that?
A No.
Q We discussed the -- remember discussions of the blue book last week?
A I do.
Q I'm going to hand you what has been marked as Exhibit 2 and ask you --
A Thank you.
Q -- is that the blue book?
A Yes, it is.
Q Please explain what the blue book is.
A This is published by the U.S. Food & Drug Administration, the FDA, and in particular -- it is a guidance document and it is called Device Labeling Guidance, given a number, G91-1, and referred to as a blue memo.
Q Is that a written standard in the industry?
A Yes, it is.
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(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.)
BY MR. GOSS:
Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005.
What is this document?
A As I mentioned, the GHTF published a number of different guidance documents that were arrived at through a number of different steps of coordination amongst industry representatives, manufacturers that means, representatives of manufacturers, and regulators from the various countries that I mentioned.
And this is one of the guidance documents that was published by GHTF in final form as one of the guidances that is important to the global model for development and marketing of medical devices. And this particular one is called Labeling for Medical Devices.
Q Is this a written standard in the industry regarding labeling?
A Yes, it is.
Q Is this the same thing that you relied upon in

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support of your opinions today?
A Yes, it is.
Q About labeling?
A Yes.
Q Did you rely upon anything in the blue book in support of your opinions today about labeling?
A Yes, I did.
Q Last week we also, I believe, marked and used -- see if I can find it here -- Exhibit 24 and Exhibit 25. Exhibit 24 being a Global Harmonization Task Force document regarding Essential Principles of Safety and Performance of Medical Devices and Exhibit 25 being a Global Harmonization Task Force document entitled Clinical Evaluation.
Did you rely on Exhibits 24 and 25 in giving your -- in reaching your opinions that you are going to give today regarding labeling?
A Yes, I did.
Q Okay. All right. What I would like to focus on is in the IFU, the Adverse Reaction section and the Precautions and Warnings sections.
Have you found those?
A Yes.
Q All right. I want to visit with you a little bit about this.

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A All right.
Q First of all, did you undertake an investigation to reach an opinion as to whether or not the -- those sections were adequate?
A Yes, I did.
Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate?
A Yes, I did.
Q And what's that conclusion?
A It was not adequate.
Q And likewise, with respect to the contraindications and -- I'm sorry, the Warnings and Precautions section, did you reach a conclusion as to whether or not that section was adequate?
A Yes, I did.
Q And what was that opinion?
A That section also is not adequate.
Q Okay. So in your investigation to determine whether or not the Adverse Reaction section, for example, was adequate, what did you do?
A I evaluated a number of documents. Of course, I start with the framework of the regulations and the applicable standard and guidance documents, which --

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some of which we discussed or we just put into evidence here.

I start with that framework, and then I looked at company documents with regard to what they knew and when they knew it. I reviewed deposition testimony about what was known. I reviewed the medical and scientific literature that was relevant. I evaluated commercial experience in the context of publicly available information that's on a web -- in a database called MAUDE, Manufacturer and User Facility Device Experience database, referred, again, to as MAUDE, M-A-U-D-E, for short, which includes serious adverse reactions and malfunctions and that can result in serious adverse reactions or be life-threatening that are reported to the FDA.

This information is available, again, publicly, so a manufacturer like Ethicon can look at competitor product adverse events that have occurred as well as their own reports and their complaint database.

Q Let me ask you a little bit about that. Is one of the things you need to know is whether Ethicon knew or should have known about a risk?

A Yes.

Q Okay. And let me back up a little bit, and let's go to the blue book which is marked as Exhibit --

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A Two.

Q -- Exhibit 2. Does the blue book provide for us what should be in the Adverse Reaction section?

A Yes, it does.

Q Okay. What page of the blue book provides that?

A On this copy it is page 12, section 8.

Q And what is that entitled?

A Adverse Reactions.

(The document referenced below was marked Deposition Exhibit 51 for identification and is appended hereto.)

BY MR. GOSS:

Q Okay. I'm going to hand you what -- I want you to keep that in front of you. I'm going to hand to you a slide that's been marked as Deposition Exhibit 51 entitled Adverse Reactions Standard. I'm going to ask you whether or not -- have you seen this slide before?

A Yes.

Q Okay. Is that standard set forth in the slide marked as Exhibit 51 the standard that's set forth in the blue book?

A Yes, it is.

Q And what does slide 51 say?

A It says that all adverse reactions reasonably

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associated with the use of the device should be included in the product label.

(The document referenced below was marked Deposition Exhibit 52 for identification and is appended hereto.)

BY MR. GOSS:

Q Okay. Now, let's go to the Warnings and Precautions section of the blue book. I'm going to ask you the same set of questions.

I'm going to hand you what's been marked as Deposition Exhibit 52. The Warnings and Precautions section, I believe, is the page before that Adverse Reaction section in the blue book.

A The warning section is on page 10 in this copy.

Q Okay. And I'm going to hand you what's been marked as Deposition Exhibit 52, and I'm going to ask you whether or not that accurately sets forth the warnings and precautions section set forth in the blue book.

A Yes.

Q What does that slide titled "Warnings and Precautions" state?

A Shall I read it?

Q Yes.

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A "Describe serious adverse reactions and potential safety hazards, the limitations in use imposed by them, and the steps that should be taken if they occur."

Secondly: "Include an appropriate warning if there is reasonable evidence of an association of a serious hazard with the use of the device. A causal relationship need not have been proved."

And thirdly: "Include information regarding any special care to be exercised by the practitioner and/or patient for the safe and effective use of the device."

Q Okay. And, again, this is from the blue book; is that right?

A Yes.

Q By the way, would slides 51 and --

A 52.

Q -- 52 assist you -- if published to the jury, would they assist you in setting forth your testimony?

A Yes.

Q Okay. Did you --

MR. GOSS: For those of you on the phone, we are

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having some trouble with my microphone right now.
(Off-the-record discussion.)
MR. GOSS: Okay. All right. We are back.
BY MR. GOSS:
Q Do you know whether or not -- first of all, strike that.
Did you see anything in your investigation that reflected whether or not Ethicon had adopted the blue book definitions you just read as their standard?
A Yes, I did.
Q And what did you review in that regard?
A In particular, the deposition of Susan Lin from the regulatory department at Ethicon.
Q Okay. I'm going to hand you what I've marked as Exhibit 53, and this is the -- on the front page says it is the August 9th, 2013, Volume III -- actually, I'm going to remove that exhibit. It was the wrong one. We will get back to the Susan Lin actual deposition itself.
But in summary, what do you recall Susan Lin testified to with respect to Ethicon and the blue book?
A That Ethicon had adopted the G91-1 blue book memo on medical device labeling as its standard to follow.
Q And is that what you would expect of a

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reasonable, prudent manufacturer?
A Yes.
Q Okay. So that's a good thing?
A That's a good thing.
Q All right. Okay. So we have gone through the blue book, we have gone through the global marketing. Has the global -- GFTG?
A GHTF.
Q G -- I'm sorry.
A That's okay.
Q GHTF.
You have described what needs to be in the Adverse Reaction section. You -- I believe your testimony was that in order to determine whether or not the 2010 Adverse Reaction section and Precautions and Warnings sections were adequate, you needed to know what Ethicon knew or should have known?
A That's correct.
Q And did you endeavor to do that?
A Yes, I did.
Q Okay. All right. I'm going to hand to you --
MR. GOSS: And for the folks on the phone, there's a slide that I forwarded to you that's entitled -- it is about a five-page slide entitled "Risk Known by Ethicon at the Time of TVT-O Launch Not in the TVT-O

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IFU," and that's where I'm going with this line of questions.
(The document referenced below was marked Deposition Exhibit 53 for identification and is appended hereto.)
BY MR. GOSS:
Q I'm going to hand to you -- first of all, did you assist in the preparation of the slide that sets forth the risks known by Ethicon at the time of the TVT-O launch that weren't in the IFU?
A Yes.
Q Would that slide assist you in presenting your testimony to the jury?
A Yes.
Q Okay. I'm going to hand you what's been marked as Deposition Exhibit 53.
A Thank you.
Q Is that the slide that you assisted in the preparation of?
A Yes.
Q Okay. Let's kind of figure out where we are on this.
So the left side of the slide says "Known Risks," the middle part of the slide says "Source," and the right part of the slide says 2010 TVT dash -- I'm

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sorry, "2010 TVT-O IFU."
First of all, what is the middle section, Source?
A On this particular slide the source reflects testimony of senior members of Ethicon's development team for the TVT-O.
Q And are these items under Source items that you relied upon in making a determination as to whether a risk was known or should have been known by Ethicon?
A Yes. And there is one source here that actually is a document in addition to the others being testimony.
Q Okay. So let's just walk through the slide.
On the first page it says "Dyspareunia." What's dyspareunia?
A Painful sex, painful intercourse.
Q And you have on the slide as your source Catherine Beath, Martin Weisberg. Who are those people?
A Catherine Beath was head of regulatory affairs, and Martin Weisberg was medical director.
Q Okay. What's regulatory affairs?
A Regulatory affairs is the part of the company that deals with -- with standards, regulations, and particularly FDA -- in particular FDA matters.

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Q So just so we are clear, as we walk through this slide, when you list, for example, Martin Weisberg's testimony, it is next to dyspareunia, what is that telling us?
A It is telling us that he -- he acknowledged that dyspareunia was a known risk.
Q At the --
MR. LEWIS: Objection. Form.
BY MR. GOSS:
Q At the time of the launch?
A Yes.
Q And when you say "acknowledge," is that what these deposition cites relate to?
A Yes. This is deposition testimony that confirms that the company knew about these risks.
Q Okay. So then it says for dyspareunia, for example, 2010 TVT-O IFU, "No."
What does that mean?
A That means that there was no listing of an adverse reaction or a warning with regard to dyspareunia in the 2010 IFU that was in use at the time of Ms. Ramirez's surgery.
Q Would a reasonable and prudent manufacturer applying the standards in the industry that we have talked about had included dyspareunia in the Adverse

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Reactions section?
A Definitely.
Q The next one is, "Vaginal scarring leading to significant decrease in quality of life," and the source is Beath deposition testimony.
Again, explain to us what that means.
A That, again, means that this was -- there was testimony that this was a known adverse event, a known risk of use of the TVT-O device, and it was not included as a risk in the 2010 IFU, which was the IFU in use at the time of Ms. Ramirez's surgery.
Q And for each of these things that are in yellow, each of these risks in yellow, what does that denote?
A This denotes that these are -- these are complications that Ms. Ramirez has been reported to have experienced.
Q Okay. And let's just go down this. So recurrence of incontinence. First of all, what is that?
A Incontinence, Ms. Ramirez had surgery for stress urinary incontinence, which is an involuntary leakage of urine with intra-abdominal pressure such as is caused by coughing or exercise, jumping, for example, and the TVT-O device is intended to treat

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stress urinary incontinence. So recurrence of incontinence would be a failure of performance of the device for its intended use.
Q And should that have been --
MR. LEWIS: Objection.
BY MR. GOSS:
Q Should that have been in the TVT-O IFU in 2010?
A Yes.
Q And would a reasonable and prudent manufacturer applying the standards in the industry have put it in the Adverse Reaction section of the IFU?
A Yes.
Q Okay. And what do you rely upon in support of their knowledge?
A In this case, as cited here, Ms. Beath's deposition testimony.
Q Okay. Let's just continue going down this.
"Inflammation/chronic foreign-body reaction." First of all, what is that?
A We were discussing earlier the chronic foreign-body reaction. The inflammation that results from that. Because polypropylene is plastic, it is a foreign body. When it is implanted in the body, the body mounts a foreign-body reaction to it, and it is --

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in contrast to what the TVT-O IFU actually said, that foreign-body reaction and inflammation can be chronic, and that can be associated with risk.
And so that was confirmed by the testimony of Dr. Hinoul, Piet Hinoul, also a medical director, and Dr. Weisberg, who we talked about also, a medical director.
MR. LEWIS: Objection. Nonresponsive.
BY MR. GOSS:
Q Who confirmed that?
A Dr. Hinoul, Dr. Piet Hinoul, and Dr. Weisberg.
Q Who is Dr. Piet Hinoul?
A Worldwide medical director at one point, if I recall correctly.
Q What's a medical director?
A In key -- in -- a physician.
Q Okay.
A He is a doctor, a physician, at Ethicon with a key role in product development providing medical input into product development, reviewing -- reviewing safety risk information, evaluating from a medical standpoint the safety and efficacy of products.
There are a number of different roles that people in -- that physicians in medical affairs will play.

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Q The slides that we marked as Exhibits 51 and 52 setting forth the adverse reaction standard and warnings and precautions standard, and I believe you testified that those came from the blue book, would these be in compliance with the Global Harmonization Task Force requirements as well?
A Yes.
Q Okay.
A Thank you.
Q Okay. Let's go to -- let's go to the next one. First of all, the inflammation and chronic foreign-body reaction, should that have been in the 2010 IFU, that risk?
A What it says in the 2010 IFU is that inflammation may result and there may be a transit -- may result -- let me see if I can find the specific language.
That "transitory local irritation at the wound site and a transitory foreign-body reaction may occur, and this response could result in inflammation." And there it says transitory, meaning brief. It does not mean chronic; so that is misleading.
Q Okay. Let's go to -- should -- should the belief -- strike that.
The risk of chronic foreign-body reaction,

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should that have been disclosed in the IFU?
A Yes. Definitely.
Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so?
A Yes.
Q Was it in the IFU?
A No.
Q Okay. Urinary tract infection, what's a urinary tract infection?
A It is infection of -- could be infection of the bladder, the urinary tract.
Q Who is your source for your opinion that Ethicon knew or should have known about urinary tract infections prior to launch?
A Dr. --
MR. LEWIS: Objection. Form.
THE WITNESS: Dr. Piet Hinoul.
BY MR. GOSS:
Q Okay. And is there anything regarding the risk of urinary tract infection in the 2010 IFU?
A No, there is not.
Q Would a reasonable and prudent manufacturer applying the standards in the industry have included urinary tract infection risk in the Adverse Reactions

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section of the 2010 IFU?
A Yes.
Q And, again, everything in yellow is something that Jennifer Ramirez has alleged that she has experienced; is that correct?
A That is correct.
Q The next known risk, "nerve damage that can cause lifelong pain."
First of all, what's that?
A It could be some type of damage to the nerve. It could be irritation of the nerve. It could be during implantation of the device, an impact on the nerve.
There are different types of damage to the nerve that could occur, but that nerve damage could be long-term and result in pain and other types of complications.
Q Is there anything in the IFU relating to long-term nerve damage that could cause lifelong pain?
A No. There is not.
Q Would a reasonable and prudent manufacturer applying the standards in the industry have included that in the IFU?
A Definitely.
Q Chronic pain is the next one.

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What does that mean?
A Chronic pain means long-term pain that just doesn't go away after a short period of time.
Q And the source is the Weisberg deposition testimony. Again, who is Weisberg?
A Medical director at Ethicon, a physician.
Q Is chronic pain listed as an adverse reaction in the 2010 IFU?
A No, it is not.
Q And would a reasonable and prudent manufacturer applying the standards in the industry have included chronic pain in the 2010 IFU?
A That definitely should have been included as a risk, yes.
Q The next one, "Chronic groin, thigh, leg, pelvic and/or abdominal pain."
Would your testimony for that be the same as your testimony for chronic pain?
A Yes.
Q And the next one, "One or more revisions may be necessary to treat adverse reactions."
Would your testimony for that be the same as your testimony for chronic pain?
A Yes.
Q And the "Adverse reactions may not resolve,"

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what does that mean?
A That means that even with treatment, some of the adverse reactions that have been reported can occur with the implantation of the TVT-O device may not be cured, may not go away.
Q And is that something -- was that included in the 2010 IFU?
A No.
Q Is that something that a reasonable and prudent manufacturer applying the standards in the industry would have included in the 2010 IFU?
A Yes, it should have been.
Q Moving on, "Additional surgeries to treat adverse reactions may not resolve those adverse reactions."
That's similar to the one we just talked about?
A That's correct.
Q Would your testimony be the same?
A Yes.
Q "De novo urinary retention."
What is that?
A Basically the bladder does not empty all of its -- all of the urine.
Q And was that a risk that your investigation

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uncovered that Ethicon knew about?
A Yes.
Q And would your testimony be the same for de novo urge incontinence?
A Yes.
Q And for de novo urinary frequency?
A Yes.
Q And what's your source for all three of those?
A Here, as noted, Dr. Weisberg's deposition testimony.
Q And were those three things addressed in the 2010 TVT-O IFU?
A No, they were not.
Q Are those three things something that a reasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU?
A Definitely.
Q Okay. Let's go to this last one in yellow. Again, what's the yellow?
A These are complications that Ms. Ramirez has reported as having experienced or is experiencing.
Q And the last one on this page, "Roping, fraying and particle loss," is that what we talked about during your deposition last week?

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A Yes.
Q Okay. You cite as your source an email from Gene Kammerer dated August 26, 2006, regarding LCM versus MCM, and a PowerPoint.
Is that the PowerPoint that we discussed last week during your deposition?
A Yes. And there are other documents with regard to roping and fraying and particle loss as well.
Q And is the PowerPoint that -- discussing -- is the PowerPoint that is reflected there the same PowerPoint that's been marked as Exhibits 31 and 32?
A Yes.
Q Okay. All right. The last page of this -- the last page of this slide has some other known risks, and I see they are not in yellow. Does that mean that these are not things that you understand Jennifer Ramirez has complained about?
A That's correct.
Q Okay. But is your testimony the same -- with respect to venous thrombosis, abscess formation, hematuria, and mesh erosion leading to significant decrease in quality of life, is your testimony about those risks the same as what we just discussed with the others?
A Yes.

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Q Okay. I would like to focus a little bit on the -- a little bit on the statements that are in the IFU. Okay. And let's go to -- I'm going to -- sometimes these IFUs are a little small in the writing. I'm not sure this one is much better.
MR. GOSS: Do the folks on the phone have what I'm about to give?
MS. DIAZ: Yes.
BY MR. GOSS:
Q I'm handing you the Warnings and Precautions sections of the IFU and the Adverse Reactions and Actions section of the IFU.
MR. GOSS: For the folks on the phone, you should have these in the stuff we sent you when we got started.
I'm marking them as a combined -- actually, I'm going to mark the Warnings and Precautions section as 54, the Adverse Reactions and Actions sections as Exhibit 55.
(The documents referenced above were marked Deposition Exhibits 54 and 55 for identification and are appended hereto.)
BY MR. GOSS:
Q I'm going to hand to you what's been marked as

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Exhibit 54. Would this slide assist you in your testimony before the jury?
A Yes, thank you.
Q Is it a little easier to read?
A It is much easier to read.
Q Okay. And would your testimony be the same for Exhibit 55?
A Yes.
Q Okay. So let's talk about -- let's talk about 54 first. Again, we have given the definitions of what should go in here. Is there -- in this Exhibit 54 regarding warnings and precautions, is it mostly precautions or is it warnings? What in here would actually be a warning?
MR. LEWIS: Objection. Form.
MR. GOSS: Let me strike that question.
BY MR. GOSS:
Q For instance, "Ensure that the tape is placed with no tension under the mid-urethra."
Is that considered a warning or a precaution?
A Yes.
Q Okay. What -- did you view all of these as a representation of some risk?
MR. LEWIS: Objection. Form.
THE WITNESS: These are appropriate. They are

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appropriate in terms of for what they state except where they are misleading, if I may say it that way.
BY MR. GOSS:
Q Okay. Are there any --
MR. LEWIS: Objection. Form.
BY MR. GOSS:
Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to be misleading?
A Yes.
Q Which ones?
A Just go down the list. The first one that I see is the fifth up from the bottom.
"Transient leg pain lasting 24 to 48 hours may occur and can usually be managed with mild analgesics."
Q Okay. And why do you find that misleading?
A Because while that may be true in a number of patients, there is clinical evidence to -- reports in the literature, for example, that, in fact, documentation and data that Ethicon had that shows that leg pain does not always resolve in 48 hours and, in fact, sometimes it is persistent and it may require opiate analgesics, for example. And it may affect gait and walking.

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So that is misleading. It leads the reader to believe that any pain that is based on implantation of the TVT-O will go away in a couple of days.
Q Is that --
A With regard to leg pain, I should say.
MR. LEWIS: Objection. Nonresponsive. Everything beginning with "leads the reader."
BY MR. GOSS:
Q Does that understate the risk?
A Yes.
Q What are -- what, if anything, is improper about understating risk?
A It is misleading. It is false. It is misleading. It puts in the mind of the reader a level of comfort, if you will, that the risk is minor when in some patients that risk is not minor.
Q Does that affect public safety?
A Yes, it does.
Q Anything else in this Warnings and Precautions section that you found misleading or understating risk?
A Let me just read through them quickly, if I might.
No.
Q Just so we are clear about what the exercise was that we just went through, is it your opinion that

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Deposition Exhibit 53, are these risks in the Warnings and Precautions section?
A Some of them should have gone in the Warnings and Precautions section, yes.
Q Okay. Where should the others have gone?
A In the Adverse -- all of them should be in -- all of those that affect patient safety should -- that are risks to the patient, I should say -- basically all of them except the fraying and the particle loss should have been listed in Adverse Reactions. And the fraying and particle loss, the adverse reactions that those can cause should go in the Adverse Reactions section.
Q Okay.
A And then those that are serious and potentially chronic, those also get included in warnings.
Q Okay. And so what I'm asking you to do now is step away from just that and let's look at what's actually in the IFU.
A Right.
Q And I'm asking you to identify for me the things that were said and whether or not they understated risk or were misleading.
Do you understand that?
A I do understand, yes.

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Q Okay. Let's go the Adverse Reaction section which is Exhibit 55.
A Right.
Q Let's just take them one at a time.
"Punctures or lacerations of vessels, nerves, bladder, or urethra, or bowel may occur during needle passage and may require surgical repair."
Is that misleading or does that understate risk?
MR. LEWIS: Objection. Form.
THE WITNESS: I don't see a problem with that one.
BY MR. GOSS:
Q Okay.
"Transitory local irritation at the wound site and transitory foreign-body response may occur. This response could result in extrusion, erosion, fistula formation, or inflammation."
Does that understate the risk?
A Yes, it does.
Q Is that misleading?
A Yes, it is.
MR. LEWIS: Objection. Form.
///

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BY MR. GOSS:
Q Why is that?
A It is misleading because, as we were talking earlier, the foreign-body response is not transitory. It is chronic. And the inflammation that can then result is chronic. So this, again, leads the reader to believe that it is brief and it will go away, and indeed that's -- the documentation testimony supports that is not the case.
Q Let's go to the next one.
"As with all foreign bodies, Prolene mesh may potentiate an existing infection. The plastic sheaths initially covering the Prolene mesh are designed to minimize the risk and contamination."
Is that misleading or an understatement of risk?
MR. LEWIS: Objection. Form.
MR. GOSS: Tell me what that is so I can cure it.
MR. LEWIS: Lack of foundation. Really, lack of foundation.
MR. GOSS: Okay. All right. I'll stick with my question.
///

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BY MR. GOSS:
Q You can answer it.
A In terms of potentiating existing infection, that is fine, but what it doesn't say is infection can result. So it is not just -- it understates that infection de novo, a new infection may occur.
Q The last one there:
"Overcorrection, too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction."
Does that -- is that misleading or does it understate risk?
MR. LEWIS: Objection. Form.
THE WITNESS: No, because here it actually states that the lower urinary tract obstruction can be permanent.
BY MR. GOSS:
Q Okay. There was some discussion last week between you and Ethicon's counsel about whether or not duration, frequency, and severity is required to be in the IFU.
Do you recall that?
A Yes, I do.
Q At times throughout this IFU, did Ethicon

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endeavor to put in duration, frequency, or severity?
A Yes, it did.
Q And typically was it when they were trying to minimize risk or identify the seriousness of risk?
A Yes.
MR. LEWIS: Object to form.
THE WITNESS: More often when they were trying to minimize risk.
BY MR. GOSS:
Q Okay.
A The only time "permanent" is used is in this last one.
Q Okay. Let's go under the Actions section.
"Animal studies show that implantation of Prolene mesh elicits a minimal inflammatory reaction..."
Again, is minimal a time -- does that address severity, duration, intensity?
A Yes, it does.
Q Okay. It "elicits a minimal inflammatory reaction in tissues, which is transient."
Again, is that dealing with severity, frequency, permanency?
A Yes, it does.
Q "...and is followed by the

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deposition of a thin fibrous layer of tissue that can grow through the interstices" --

Is that right?

A Yes.

Q -- "of the mesh, thus incorporating mesh into the adjacent tissue."

This is -- this is what I want you to focus on:

"The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes."

Does that -- is that misleading or does it underplay risk?

MR. LEWIS: Objection. Form.

THE WITNESS: It is both.

BY MR. GOSS:

Q Okay. Explain.

A It is false and misleading and underplays the risk because Ethicon has in its own files, as well as there are publications, showing that polypropylene is indeed subject to degradation.

Q Did you see -- in your investigation into Ethicon's conduct, did you see any discussions by

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Ethicon internally regarding degradation?

A Yes, I did.

Q Did you read any testimony by Ethicon scientists regarding degradation?

A Yes.

Q Do you understand Thomas Barbolt to be a scientist at Ethicon?

A Yes.

Q Did you read any testimony of Thomas Barbolt?

A Yes, I did.

(The document referenced below was marked Deposition Exhibit 56 for identification and is appended hereto.)

BY MR. GOSS:

Q I'm going to hand you what's been marked as Exhibit 56 to your deposition. And this is a deposition transcript dated January 8th, 2014, for Thomas A. Barbolt, Ph.D., given in the MDL.

Is this document, 56, one of the deposition transcripts that you reviewed in your investigation of Ethicon's conduct?

A Yes, it is.

Q And is that something that you relied upon in whole or in part for giving your opinions?

A Yes.

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(The document referenced below was marked Deposition Exhibit 57 for identification and is appended hereto.)

BY MR. GOSS:

Q I'm going to ask you -- I'm going to direct you to page 409 for this transcript, in particular beginning with line 1 of page 409 through line 13 of page 409. And I'm going to also hand you Deposition Exhibit 57, which is a slide of that deposition testimony.

Will this slide assist you in your -- have you seen this slide before?

A Yes, I have.

Q Will it assist you in giving your testimony to the jury?

A Yes.

Q Okay. Would you please read the slide for me.

A Yes.

"Question: And that's Ethicon's position as you -- as the spokesperson for Ethicon, it is Ethicon's position that degradation, surface degradation, can occur; correct?

The witness states, Dr. Barbolt, "Yes."

"Question: And this was known well

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in advance of this statement that the material is not absorbed nor is it subject to degradation; correct?

"Answer: Yes. This is from 1992."

Q And why do you find that important, if at all?

A It is important because what's included -- this is stating that from 1992 the company was aware that polypropylene is subject to degradation, yet in the IFU, again, the primary communication between the company and the doctor, which is supposed to give the doctor all the information necessary to use the product safely and effectively and to make decisions as to what is the best treatment to use for a particular patient, that's not what is stated in the IFU.

Q And then picking up with lines 21 through lines 4 on the next page, could you read that, please, from the slide.

A "Question: Okay. And, number two, we know from what we have seen in the internal studies by Ethicon that the Prolene and the TVT mesh is susceptible to surface degradation; correct? Yes, Doctor?

"Answer: Yes."

Q And why is that important, if at all?

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A Again, it shows --
MR. LEWIS: Objection. Form.
THE WITNESS: -- that the information in the IFU was false and misleading.
BY MR. GOSS:
Q Okay.
A And that's in violation of the standard of care.
Q Okay. Thank you. All right.
MR. LEWIS: Objection. Nonresponsive.
BY MR. GOSS:
Q I want to talk a little bit -- we have been through the IFU, I want to talk with you a little bit about some -- the knowledge, if any, that Ethicon had regarding chronic pain and dyspareunia.
You have spoken a little bit about transitory. What does transitory mean?
A Brief.
Q And we have spoken a little bit about chronic. What does chronic mean?
A Persistent, long-term.
Q Is chronic just the opposite of transitory?
A Yes.
Q Okay. Did you review any testimony from Ethicon scientists prior to 2010 when Jennifer Ramirez

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was implanted with the TVT-O where those scientists discussed whether or not potential adverse reactions were transitory?
A Yes.
Q And did you review David Robinson's testimony?
A Yes.
Q Who is David Robinson?
A He is also a physician and medical director at Ethicon.
Q Did you review Piet Hinoul's testimony?
A Yes.
Q Who is Piet Hinoul?
A Another physician, medical director as well, at Ethicon.
Q Did you review James Hart's testimony?
A Yes.
Q Do you recall who James Hart was?
A He was also a medical director.
(The document referenced below was marked Deposition Exhibit 58 for identification and is appended hereto.)
BY MR. GOSS:
Q Okay. Okay. I'm going to first hand you what's been marked as Exhibit 58. It says it is the deposition of David Robinson, Volume III, dated

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September 11th, 2013.
Is this one of the deposition transcripts that you reviewed in forming your opinions in this case?
A Yes, it is.
Q And let me refer you to page 355. just a moment.
Okay. Let me refer you to page 1139, beginning with line 20, and through 1140, page 1140, ending with line 16. Okay. I'm sorry, 1139, line 15 is where I want you to pick up.
I'm going to ask you whether or not you read that -- if that testimony is any testimony that you reviewed and relied upon in forming your opinions in this case.
A Yes.
(The document referenced below was marked Deposition Exhibit 59 for identification and is appended hereto.)
BY MR. GOSS:
Q And why don't you read the question and answer to the jury -- let me do it this way. Let me show you what's been marked as Exhibit 59. Is this a slide that you have reviewed that would assist you in your testimony to the jury?
A Yes.

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Q Okay. And is that the testimony -- the testimony that you relied upon in the deposition exhibit?
A Yes.
Q Okay. Why don't you read that for the jury, please.
A "Question: Now, we talked some about the fact that women who have the TVT implanted can suffer from what's called dyspareunia or, in other words painful sex; correct?
"Answer: Yes.
"Question: Did you warn physicians that patients could have implantation of the TVT mesh and that could cause permanent painful sex?
"Answer: We did warn against organ damage, the word 'intercourse' and 'pain' did not appear."
Q Why is that important, if at all?
A Because one cannot infer from organ damage permanent painful sex. The permanent painful sex, that potential risk, needed to be stated in the IFU.
Q All right. I'm going to shift gears to another deposition. Let's shift gears again.

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A Is this a good time for a quick break?
Q Right. I think we have been going for almost an hour and 15 minutes. Why don't we take about a ten-minute break. Is that fine?
MR. LEWIS: That sounds fine.
MS. VERBEEK: Sounds good.
VIDEO OPERATOR SISSON: This will end Disk 1, Volume II, in the deposition of Peggy Pence. 11:37, we are off the record.
(Recess taken.)
VIDEO OPERATOR SISSON: At 11:52 we are back on the record with the beginning of Disk 2, Volume II, in the deposition of Peggy Pence.
Counsel, after you.
MR. GOSS: Thank you.
BY MR. GOSS:
Q Okay. Dr. Pence, we are back on the record. There was some discussion before we went off the record about the IFU and Ethicon's knowledge regarding chronic foreign-body reactions and chronic inflammatory responses.
Do you recall that line of questioning?
A Yes, I do.
(The document referenced below was marked Deposition Exhibit 60 for

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identification and is appended hereto.)
BY MR. GOSS:
Q Okay. I'm going to hand you what's been marked as Exhibit 60.
Did you review the deposition of Piet Hinoul dated January 14th, 2014, that's been marked as Deposition Exhibit 60 in forming your opinions in this case?
A Yes, I did.
Q And is that deposition transcript in whole or in part something that you relied upon to form your opinions?
A Yes, it is.
Q I'd ask you to turn to page -- page 11 -- I'm sorry, page 1144. Okay. And refer you to lines 11, 12, and 13.
Do you see there?
A Yes, I do.
Q Does it start out "foreign-body reaction"?
A Yes.
(The document referenced below was marked Deposition Exhibit 61 for identification and is appended hereto.)
BY MR. GOSS:
Q Okay. Would you please read those -- first of

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all, let me mark as Exhibit 61 a slide. I believe you have seen this slide before, Exhibit 61?
A Yes.
Q Would that assist you in describing -- would that assist you in your testimony to the jury?
A Yes.
Q What is that slide?
A It is -- it is testimony from Dr. Piet Hinoul.
Q Is it testimony that's before you in the transcript?
A Yes.
Q Okay. Would you please read the testimony that you relied upon of Dr. Hinoul.
A From the slide?
Q Yes.
A The question is:
"The foreign-body reaction or the foreign-body response is chronic; correct?
"Answer: Yes. It is a chronic -- it is a chronic foreign-body reaction."
Q And why, if at all, do you find that important?
A Again, because as we noted earlier in the IFU, it says that it is transitory, not chronic, and, as we

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discussed earlier, chronic foreign-body response/chronic inflammation can also lead to complications that may be chronic.
Q Okay. In that same deposition transcript I'm going to ask you to turn to page 1156, lines 1 through 9. Are you there?
A Yes.
Q And is that testimony testimony that you relied upon in forming your opinions in this case?
A Yes, it is.
(The document referenced below was marked Deposition Exhibit 62 for identification and is appended hereto.)
BY MR. GOSS:
Q And I'm going to hand you what's been marked as Deposition Exhibit 62. Is that a slide that reflects that deposition testimony?
A Yes, it is.
Q Would that assist you in your testimony before the jury?
A Yes.
Q Could you please read for the jury what testimony you relied upon in forming your opinions?
A Okay. Again, this is Dr. Piet Hinoul's testimony. The question to Dr. Hinoul is:

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"And scientists who are expert in this field the most expert people in the world --
"Answer: Mm-hmm.
"Question: -- would agree that there is a chronic inflammatory response to the --
"Answer: Yes.
"Question: -- TVT mesh; correct?
"Answer: Correct."
Q Okay. And why, if at all, did you find that important?
A Again, it substantiates that the -- what we were discussing earlier. It supports that the inflammatory reaction is chronic, it is supported by scientists who are expert in the field, and Dr. Hinoul testifies that that is the case, and it is -- the chronic inflammatory response is not what's stated in the IFU.
Q And is that -- that information -- the testimony that -- the two pieces of testimony that you just read, did your investigation determine whether or not that was information that Ethicon had in its possession at the time of launch?
A Yes.

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Q Okay.
MR. LEWIS: Objection. Form.
(The document referenced below was marked Deposition Exhibit 63 for identification and is appended hereto.)
BY MR. GOSS:
Q Let me see the transcript again.
I'm going to hand you back Dr. Hinoul's testimony that you previously stated that you reviewed, and I'm going to ask you to turn to page 1170, lines 1 through 6, of that testimony. I'm going to ask you to review that testimony and tell the jury whether that is something that you relied upon in forming your opinions in this case.
A Page 1170; is that correct?
Q That's correct.
A Okay.
"Question: And the doctor would be expected to believe, pursuant to what it states here, that the inflammatory reaction is only transient because that's all it says; correct?
"Answer: Correct."
Q Is that what's reflected in Exhibit 63, and would Exhibit 63 assist you in your -- giving your

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testimony to the jury?
A Yes.
Q Okay. Why did you find -- and, again, read Exhibit 63.
A "Question: And the doctor would be expected to believe, pursuant to what it states here, that the inflammatory reaction is only transient because that's all it says; correct?
"Answer: Correct."
Q And why is that important?
A Again, because the IFU is misleading. The IFU doesn't tell the doctor that the -- there is the -- a chronic inflammatory reaction, chronic foreign-body response, and, therefore, it is -- again, it is misleading to the doctor in terms of having all the information necessary for safe and effective use of the device and for making a decision as to whether or not this device is the appropriate treatment for the patient's stress urinary incontinence.
MR. LEWIS: Objection. Nonresponsive.
BY MR. GOSS:
Q Okay. This morning, as you will remember, I wanted to start back up where we left off last time, but we didn't have the exhibit here.

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Do you recall?
A Yes, I do.
Q So I'm going to back up a little bit and discuss where we left off last week.
Do you remember some discussion at the end of the deposition last week about a particular lot of mesh that had some problems?
A Yes.
Q Okay. And one of the things we did last week was we marked the surgical record for Jennifer Ramirez.
Do you recall that?
A I do.
Q Let me see if I can find this stack. I'm going to hand you what's been marked as Exhibit 19. And, again, tell the jury what is Exhibit 19?
A This is a one-page document. It is the surgery implant record from Baptist Health System with the sticker on it from the TVT-O device that was implanted in Ms. Ramirez.
Q Okay. And then what does it say is the lot number for that?
A The lot number of TVT-O is 3405428.
Q And what is the 810081 number?
A That is the product number that designates that the material is TVT-O.

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Q And, in your investigation into Ethicon files, did you see any documents where Ethicon had received any complaints about that particular lot number that is Jennifer Ramirez's lot number?
A Yes, I did.
Q And we touched on this a little bit last week, but do you recall the presentation set forth in Exhibit 42 of last week?
A Yes, I do.
Q And what is that document?
A This is a PowerPoint presentation entitled "Particle and TVT-O Blisters."
Q And what do you understand that document is reflecting?
A It is discussing the particle loss that has -- complaints of particle loss that have been reported to Ethicon, in particular for the mechanically cut TVT-O device.
Q Is Jennifer Ramirez's lot number one of the lot numbers for which they had complaints?
A Yes, it is.
Q And how do you know that?
A Because, as I just read, the lot number that was implanted in her is 3405428, and on this PowerPoint presentation in a listing of complaints that number

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is -- is identified.
Q Okay. And you have talked generally about there were complaints. How many complaints were there?
A For her particular lot, there were two.
Q Okay. And what -- were there other complaints for other lots?
A Yes.
Q And how many were there?
A This designates six different complaints.
Q Okay. And were they different complaints or were they making the same allegation?
A They were all making the allegation of foreign matter in the TVT-O blisters.
Q Okay. What does that mean "foreign matter in a blister"? Explain to the jury what a blister is.
A What they are talking about, the blister is the packaging in which the device -- the plastic container, if you will, in which the device is packaged, and that is opened --
Q Okay.
A -- to remove the device, and foreign matter is something in the packaging that is not supposed to be there.
Q What was the foreign matter they were complaining about?

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A What turned out to be the foreign matter, for example, in the case of Ms. Ramirez, was particles lost. We talked earlier about fraying and particle loss from the mechanically cut mesh. It is particles lost from that.
Q And was it in the open or unopened package?
A Unopened package.
Q Okay. Is the package clear?
A Yes.
Q Okay. And I gather then what you are saying is that you can see particle loss through the unopened clear package?
A Yes.
Q And how is that -- were those complaints resolved?
A The complaints were reported to Ethicon, and Ethicon, for example, they -- the same hospital that reported the two complaints for the lot number that was implanted in Ms. Ramirez also reported two other lot numbers that had the same issue in a complaint which then was investigated, and the results of the investigation were recorded in an Issue Report.
Q Okay. What's an Issue Report?
A An Issue Report is once -- it is the form at Ethicon in which they document the complaint and

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results of their investigation of a particular complaint and whether or not that investigation results in a determination that the complaint should also be reported as a Medical Device Report meaning that it is a report of a serious injury or a life-threatening injury or a malfunction that, if it were to recur, could result in a serious or life-threatening injury.
MR. GOSS: The folks on the phone, I'm asking my associate. Have we sent them the Issue Report?
MS. DIAZ: Yeah, we did.
MR. GOSS: So this was in --
MS. DIAZ: Uh-huh.
(The document referenced below was marked Deposition Exhibit 64 for identification and is appended hereto.)
BY MR. GOSS:
Q Okay. I'm going to mark as Exhibit 4 [sic] a document entitled Issue Report.
Dr. Pence, can you please explain to the jury what this is?
A Yes. This is the Issue Report that is associated with complaint CC1007, 005, which is the complaint that Ethicon received for the particular lot number that was implanted in Ms. Ramirez.
Q Okay. And did you rely upon this Issue Report

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in forming your opinions in this case?
A Yes.
Q Okay. Is there anything in particular in the Issue Report that you relied upon?
A Yes.
Q What is that?
A There was a confirmation. For example, there is a question asked in the Issue Report: "Was it determined that a device-related or patient-related event actually did occur?" And the answer was "Yes."
MR. GOSS: Let the record reflect that is from Bates page 02656826, question 2.
BY MR. GOSS:
Q Why did you find that important?
A Because it confirms that there was an issue with -- that the complaint was confirmed, if you will.
Q Is there anything else in this document that you relied upon in forming your opinions?
A Yes. On question 9. The question -- Bates number ending in 827, the question is:
"Does the information reasonably suggest that the device failed to meet its performance specification or otherwise failed to perform as intended?"
And the response is, "Yes."
Q And why, if any -- strike that.

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Why did you find that important, if at all?
A Again, it is confirmation in the investigation of this complaint that the device failed to meet its performance specifications according to those that were investigating the complaint.
Q Anything else in this report that you found important to your opinions?
A Yes. The next question:
"Does information or a medical rationale exist that states no possibility of death or serious injury occurring as a result of any recurrence of the malfunction?"
And the response is, "No."
Q What does that mean?
A Basically the reason that this is important is because, as I believe we discussed previously last week, that Ethicon had not undertaken any investigation to determine whether or not lost particles or the fraying that results in the lost particles would have a safety impact on the patient.
Q What page number were you reading from, Bates page?
A Bates ending in 827.
Q Okay. I'm going to ask you about -- kind of

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speed things up a little bit here. Let me ask you about the test results on page -- it is page 350 of 723 of this document that has the last three Bates numbers 831. It says:
"Test results. The blister contains some particles. These particles come from the mesh and are inferior to three millimeters in length. These kind of particles are not considered as foreign matter."
My question is what's the significance, if any, of three millimeters?
MR. LEWIS: Objection. Form.
THE WITNESS: That was a determination, a cutoff, that Ethicon made to decide when particle loss was an issue. I did look to see if I could identify any evidence as to why three millimeters, why that was a cutoff and not two millimeters, for example. And I was not able to find any evidence supporting why three millimeters was used as a cutoff.
BY MR. GOSS:
Q Did you see any discussion of any scientific or clinical basis for the use of three millimeters as a cutoff?
A No, I did not.

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Q Would a reasonable and prudent manufacturer arbitrarily set a cutoff of three millimeters?
A No.
Q And if that's what -- if there is no scientific basis or clinical basis for saying the cutoff is at three millimeters or whether or not particles are clinically significant, would that be a violation of standards in the industry?
A Absolutely.
Q Okay. Let's move on a little bit. Let's shift gears to the MAUDE database.
Tell the jury what the MAUDE database is.
A The MAUDE database -- MAUDE stands for Manufacturer and User Facility Device Experience database. It is the database into which medical device reports are submitted and the information for those medical device reports is recorded therein. It is publicly available -- and when I'm talking about medical device reports, those are reports of serious or life-threatening injuries to patients or device malfunctions which, if they were to recur, could result in serious or life-threatening injuries to the patient.
Post -- it is for postmarketing safety information, and it is from -- postmarketing adverse event reporting is a mechanism which is used to

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continue to evaluate postmarketing safety and performance of a medical device. It is a part of risk assessment and ongoing risk analysis so that any performance or safety issues that occur are evaluated and fed back into the risk analysis on an ongoing basis for a medical device that is in commercial use to determine if anything needs to be done to mitigate any risk. For example, changes in labeling or additional testing.

Q Okay. And so did you undertake to review the MAUDE database?

A Yes, I did.

Q And is that reflected in your report?

A Yes, it is.

Q Okay. And I think we marked your report as Exhibit 7 last week, and Exhibit 7 here -- I'm sorry, it is not Exhibit 7. It is -- I'm going to refer you to Exhibit 3, which is your report. And you recall your report had a number of tables that reflected the results of your analysis of the MAUDE database?

A Yes, I do.

Q Okay. And did you assist in the preparation of some slides that reflect those findings and those tables?

A Yes.

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(The document referenced below was marked Deposition Exhibit 65 for identification and is appended hereto.)

BY MR. GOSS:

Q Okay. I'm going to mark -- I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables.

A Yes, it does.

Q And will this slide assist you in giving your testimony to the jury?

A Yes.

Q Okay. What is Exhibit 65?

A Exhibit 65, on the left-hand side is a tabulation of the --

Q First of all, what is it entitled?

A Oh. Sorry. "Ethicon Tension-Free Vaginal Tape MDRs," standing for Medical Device Reports, "Most Commonly Reported Adverse Events from 1999 to 2010."

Q Okay. I'm going to now -- give me one second. I'm going to hand you -- what was that last number?

A 65.

(The document referenced below was marked Deposition Exhibit 66 for identification and is appended hereto.)

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BY MR. GOSS:

Q I'm going to hand you Deposition Exhibit 66. As I understand it 65 -- 65 includes TVT prior to TVT-O; correct?

A Correct.

Q Okay. I'm going to hand you what's been marked as Exhibit 66 and ask you if this is a slide that will assist you in the giving of your testimony to the jury.

A Yes.

Q And what is that exhibit?

A This exhibit is similar to the one that we were just discussing, but this one is specific to TVT-O. It is entitled Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events 2004 to 2011." The reason it starts in 2004 is because that's consistent with the time frame of the marketing of the TVT-O.

Q Okay. All right. Let me walk you through Exhibit 66.

A Okay.

Q All right. Again, this is the commonly reported adverse events from 2004 through 2011; right?

A Yes.

Q The -- the first event, pain, let's just walk

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across this. What's the 175 number?

A That's the total number of medical device reports that included a report of pain.

Q And then what is -- and is that a total number from 2004 through 2011?

A Yes.

Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right?

A That's correct.

Q And those are all events?

A Yes.

Q Okay. What is -- the numbers in red, what are those?

A That number reflects what the actual incidence could be if -- based on consideration that we know that there's underreporting of events --

Q How do we know that?

A -- to the MAUDE database.

It is published in the scientific medical literature, and there is a report, for example, from FDA that Congress -- that reflects that Congress estimates that, for medical devices, as few as 1 in 100 actual occurrences of medical device adverse events may be reported.

Q So just walk me through this for pain.

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A Okay.
Q So if there's 175 actual -- I'm sorry, if there are 175 reported events to the MAUDE database --
A Right.
Q -- based upon the studies and the congressional reports that you have just discussed, what would they estimate to be the potential adverse events that are actually out there relating to pain?
A 17,500.
Q Okay. And so for erosion with 159 reports, what's the potential number of reports based -- if you extrapolate based upon this literature that you have just discussed and the congressional information that you discussed, what's the potential erosion adverse events?
A 15,900.
Q And let's go to sexual dysfunction and walk us across the chart for that one.
A There were 57 reports of sexual dysfunction, and that would be using the 1 in 100. There would be potentially 5,700 actual reports of sexual dysfunction.
Q And if it were 10 in 100, what would it be?
A It would be --
Q The next column?
A Oh, I'm sorry. You are talking about

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10 percent. Yes.
Q Yes.
A It would be 570.
Q So the column with 1 percent assumes 1 percent would get reported, and the column with 10 percent on the far end assumes 10 percent would be reported?
A That's correct.
Q Vaginal scarring, walk us across on that one.
A Vaginal scarring, there were 23 reports. If -- if 1 in 100 only were reported, there would be 2300 actual reports.
Q Okay. All right. So -- and that's Exhibit Number?
A 66.
(The document referenced below was marked Deposition Exhibit 67 for identification and is appended hereto.)
BY MR. GOSS:
Q Okay. I'm going to hand you what's been marked as Exhibit 67 and ask you to describe -- first of all, is Exhibit 67 a slide that you helped assist in preparing?
A Yes.
Q And will that assist you in your testimony?
A Yes.

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Q Okay. Let's talk about Exhibit 67. Again, is this the information that was in one of your tables in your report?
A Yes. In an exhibit to my report, yes.
Q And is the information gathered from the MAUDE database?
A That's correct.
Q Okay. And so what is this exhibit?
A This is a breakdown of the 57 reports of sexual dysfunction that we identified in the MAUDE database into what those 57 reports -- the terms that were reported, the actual description of the events that were reported in those 57 reports.
Q Okay. And so we know that Jennifer Ramirez had her surgery in 2010?
A Correct.
Q So if we -- and this relates to sexual dysfunction; right?
A Yes.
Q Would that include dyspareunia?
A Yes.
Q Would it include the complaints that she -- one of the complaints that she is making?
A That's correct.
Q And can we determine from this table and this

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report the number of actual reports that were made from 2010 and prior to 2010?
A There were 17 reports of dyspareunia to the MAUDE database prior -- through 2010.
Q Let's just talk about the number of total reports first.
A Oh, I'm sorry.
Q Would it be 57 minus the 33 from 2011?
A That's correct.
Q So would the 24 total dysfunction reports from 2010 and prior?
A Yes.
Q And walk us across -- for example, in 2008 where there were six reports, walk us across that line and tell us what that is.
A There were six total reports, and in those six total reports there were three reports of dyspareunia, or painful sex, five reports of impaired physical relationship, so that there were a total of eight events reported in those six reports.
Q What's the difference in dyspareunia and impaired physical relationships?
A The dyspareunia is actual painful sex. Impaired physical relationship means that the -- the patient is experiencing some impact on the

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relationship with their -- with their partner as a result of what their -- the sexual dysfunction they are experiencing.
Q Okay. Then on the right-hand side the only 1 percent reporting, is that, again, based upon the testimony you just gave us relating to a potential of only 1 percent reporting rate in the United States?
A Yes, that's correct.
Q And so if there were a total of 6200 total report -- I'm sorry, the 6200 potential reports, that includes from 2004 through 2011?
A Yes. And I might clarify that the 6200 is actual events because --
Q I got it.
A The 57 is the numbers of patients --
Q Right.
A -- which 100 would be 5700 patients, but patients experience multiple events.
Q Okay. If you subtracted the 2011 -- if you added up just 2004 through 2010 potential reports of sexual dysfunction, would it be 2800?
A Yes.
Q Okay. Is that something that a reasonable and prudent manufacturer should consider significant?
A Yes.

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Q And what -- with this information, what would a reasonable and prudent manufacturer do?
A Factor this into the risk analysis and mitigate risk and certainly include it in a warning.
Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 -- 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning?
A No.
Q Okay.
MR. LEWIS: Objection. Form.
BY MR. GOSS:
Q Would a reasonable and prudent manufacturer have done so?
A Yes, definitely.
Q And was it a violation of the standard of care as set forth in the Global Harmonization Task Force documents for Ethicon not to have done so?
A Absolutely.
Q All right. Let's talk a little bit about postmarket surveillance. Explain to the jury what postmarket surveillance is.
A Postmarket surveillance encompasses just the type of information that we were talking about, complaint reporting, medical device reports, commercial

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experience with the product once it is on the market. So it includes the complaints that we have been talking about, medical device reports, reports in the scientific and medical literature. It can also include postmarketing studies and assessment of those with the idea being that once the product is on the market and the product has wide use, the company has the responsibility to constantly be assessing safety and performance to ensure that there always remains a favorable benefit-to-risk ratio for use of the device and that the risks are acceptable. And when safety issues arise, or performance issues arise, that that information is factored back into a risk analysis and appropriate actions are undertaken, such as I mentioned earlier, changing labeling, doing new studies to better understand the safety profile of the product.
MR. LEWIS: Objection. Nonresponsive.
BY MR. GOSS:
Q Okay. Does the Global Harmonization Task Force documents set forth some standards regarding postmarket surveillance?
A Yes.
MR. GOSS: Give me one second, I apologize.
(The document referenced below was marked Deposition Exhibit 68 for

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identification and is appended hereto.)
BY MR. GOSS:
Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68?
A Exhibit 68 is a guidance document -- final guidance document produced by the Global Harmonization Task Force entitled Principles of Conformity Assessment for Medical Devices.
Q And what is it dated?
A June 26th, 2006.
Q And is this a standard -- does this document reflect standards in the industry?
A Yes, it does.
Q I'll reference you to page 9 of that document where it discusses systems for postmarket surveillance. It says 5.1.2.
A Yes.
Q What is that about? Tell me what that means.
A This is stating that a medical device manufacturer, prior to actually commercializing its product, must have in place as part of what in the industry we call the quality management system a

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process to assure the continued conformity of the device to the essential principles of safety and performance. And part of the essential principles of safety and performance means that one must all -- as I was saying earlier, one must always assure, meaning the company must always assure that there is a favorable benefit-to-risk ratio for the device and that risk must be acceptable. And so they must have a system in place to assess the continued conformity of the device to the essential principles of safety and performance, basically to ensure that the product continues to have a favorable benefit-to-risk ratio throughout the postmarketing phase of the product.

Q Okay. So, as I understand it, a manufacturer simply needs to have a system in place to monitor its products. Is that one thing?

A Yes, and that includes what I was discussing a little bit earlier, complaint handling, the postmarket vigilance reporting, like the medical device reports that we were just discussing, and then taking appropriate actions based on the findings from postmarket surveillance.

Q Was that standard in the industry even before the Global Harmonization Task Force final document came out?

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A Yes.

Q Okay. Let me ask you about that.

I mean, as I understand the Global Harmonization Task Force document, I mean that was -- were those guidelines typically combining standards in the industry that already existed to try to uniform -- make them uniform?

A To harmonize them across the different regions, yes.

Q Was its intent to come up with new standards?

MR. LEWIS: Objection. Form.

THE WITNESS: It was basically evaluating the standards that existing -- existed and ensuring that all the participating parties could agree on the most optimal framework from global medical device development.

BY MR. GOSS:

Q Let me ask you with respect to Ethicon's conduct in its postmarket surveillance conduct, did you review any testimony in your investigation reflecting Ethicon's ability to monitor its laser-cut, mechanically cut, mesh products?

A Yes, I did.

MR. LEWIS: Objection. Form.

MR. GOSS: What's the objection -- elaborate on

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that so I can cure it.

MR. LEWIS: Foundation. Calls for speculation.

MR. GOSS: Okay.

BY MR. GOSS:

Q You can answer the question.

A Yes, I did.

Q Okay. And did you review the deposition of Piet Hinoul?

A Yes, I did.

Q I'm going to hand you what has previously been marked in this deposition as Exhibit 40, and this is what was identified last week as the March 27, 2014, deposition -- I'm sorry, trial proceedings testimony of Piet Hinoul in the Linda Batiste trial in Dallas, Texas.

Do you recall his testimony in that?

A Yes, I do.

Q Is that testimony something that you reviewed in preparation for your opinions?

A Yes.

Q Do they form the basis of your opinions?

A Yes.

Q Okay. I want you to look at page 41, line 13 through 20, and then lines -- page 43, lines 6 through 16. So let's start with 41, lines 13 through 20.

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Do you see where it picks up with. "Question: Right. And there is"?

A Correct.

Q Okay. I want you to read that excerpt, but then I want you to also go to page 43, lines 6 through 16, where it picks up with, "Question: Because your company..."

Do you see that?

A Yes.

Q And what's our next slide, 69 -- next exhibit, 69?

THE REPORTER: Yes.

(The document referenced below was marked Deposition Exhibit 69 for identification and is appended hereto.)

BY MR. GOSS:

Q Are both those excerpts excerpts that you relied upon in forming your opinions?

A Yes, that's correct.

Q And -- I'm going to hand you what's been marked as Deposition Exhibit Number 69. Is that a slide that you assisted in the preparation of?

A Yes.

Q Would that assist you in giving your testimony to the jury?

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A Yes.
Q Okay. And does that slide reflect the testimony in Pete Hinoul's trial testimony that you just reviewed for pages 41, lines 13 through 20, and 43, lines 6 through 16?
A Yes.
Q Okay. Would you please read that to the jury?
A "Question: Right. And there is a lot of reports that you get internally from doctors or patients saying, 'I've had an erosion' or 'My patient has had an erosion,' and it turns out that you, your company, doesn't ever know if it's laser-cut mesh or mechanically cut mesh; correct?
"Answer: If you don't know the identification number, you wouldn't know. I agree.
"Question: Because your company doesn't necessarily have all of the information from the reports on which it is laser-cut or mechanically cut mesh?
"Answer: Right.
"Question: You cannot do analysis accurately or say you have done an

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analysis accurately to determine whether or not there's an increase or decrease of erosions related to laser-cut mesh; correct?
"Answer: That's right."
Q What's the importance, if any, of what you just read?
A The importance of this is that the company was not evaluating -- in this case it is discussing erosion, but it would be applicable to other adverse events as well, to distinguish the safety profile of laser-cut mesh versus the mechanically cut mesh that was implanted in Ms. Ramirez.
Q Does that violate the Global Harmonization Task Force document you just discussed regarding postmarket surveillance systems?
A Yes.
Q Why is that?
MR. LEWIS: Objection. Form.
THE WITNESS: For example, because we know that from testimony and documentation we have discussed previously that the mechanically cut mesh has a defect of fraying and particle loss, and in order to evaluate whether or not that has an impact on patient safety, one needs to be following that versus laser-cut mesh or

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doing testing a variety of ways in which that can be assessed, and without those mechanisms in place and an appropriate investigation, then elucidating, understanding the safety profile is not possible.
BY MR. GOSS:
Q And I guess, along those lines, what I really want to direct you to and for you to direct your response to is the standards set forth in the Global Harmonization Task Force documents, the one we just looked at, 5.1.2, regarding systems and safety items and monitoring systems in place. Does the testimony that you just read from Piet Hinoul regarding the ability or inability to track laser-cut mesh or mechanically cut mesh complaints, is that violative of the Global Harmonization Task Force requirements regarding systems for postmarket surveillance?
A Yes.
Q Okay. Why is that?
A Because one -- according to the GHTF document that we were reading, in order to be able to assess the product you have to have postmarket systems in place, and there was the mechanically cut mesh product and the laser-cut mesh product and as a result you needed to have a system in place for both to be able to track postmarkets and do an appropriate postmarket

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surveillance.
Q Let's shift gears a little bit. You spoke a little bit last week, you mentioned a registry. Was there a permanent registry -- strike that.
First of all, what is a registry?
A A registry is a type of clinical study in which patients who are implanted, in this case patients who would be implanted with the TVT-O, would be enrolled and if they consented to be enrolled would be enrolled and followed long-term to determine how the product performed and whether -- and what safety issues might arise in the women who participated in the registry. It provides -- its key purpose would be to provide long-term safety data.
Q Okay. Tell me, was there ever a permanent registry for TVT mesh?
A No.
Q Would a reasonable and prudent manufacturer have instituted a permanent registry?
A A long-term registry, absolutely, yes.
Q Is that part -- appropriate postmarket surveillance?
A That would be, especially for a permanent implant, absolutely.
Q There's some questions that you received last

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week regarding whether there were over 1,000 studies on TVT.

Do you remember that?

A Yes, I do.

Q The studies that were referenced, do any of those distinguish between laser-cut mesh versus mechanically cut mesh?

A No.

Q Have you ever seen a study that Ethicon has performed to distinguish between laser-cut mesh and mechanically cut mesh?

A Not directed specifically to that question, no.

Q Were all these studies that are in that big number that's thrown out there, were they all -- do they all have safety as their end point?

A No.

Q What were -- tell the jury what an end point is.

A The end point is basically what you are evaluating, what you are trying -- the outcome you are going to evaluate at the end of a clinical study.

Q So all these -- this big number that's thrown out of the number of studies, they are not all studying safety?

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A No. They were -- much more focused on efficacy evaluations.

Q What does that mean, "efficacy evaluations"?

A Whether or not the product works and is effective for its intended purpose, in this case for stress urinary incontinence.

Q Does an efficacy evaluation evaluate safety?

A No.

Q Okay. Were some of those studies investigator studies?

A Yes.

Q What does that mean?

A Investigator initiated?

Q Yeah.

A Most of them were investigator-initiated studies, to the best of my recollection as I sit here today. That means that a physician who is utilizing the product implements a study in his patients or groups with another physician or several physicians to evaluate their patients in a study and report that data, but it is initiated by the investigator, not the company, in this case Ethicon.

MR. GOSS: Hey, everyone on the phone, if I can take five minutes -- a five-minute break to go through my notes, I think I might be just about done. So do

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y'all mind taking five minutes?

MR. LEWIS: That's fine.

MS. VERBEEK: Sounds good.

MR. GOSS: Let me take five minutes, give me a chance to go through, and I think we may be within five minutes of being done.

VIDEO OPERATOR SISSON: 12:47, we are off the record.

(Recess taken.)

VIDEO OPERATOR SISSON: Back at 12:55, we are back on the record.

BY MR. GOSS:

Q Couple things, Dr. Pence. I think when we went off the record you had discussed investigator-initiated studies?

A Yes.

Q And you described what that is. Why is it significant if the study is an investigator-initiated study, if at all?

A It is different from a company-initiated study where the company actually monitors it because when a company conducts a study, a company is required to meet a certain set of standards, which we call good clinical practices, and there are checks and balances in those standards, one of which is that the company is required

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to monitor the investigation and, for example, the data. The -- people actually go to the site where the study is being conducted and they check the data that's in the patient record versus the information that's being reported and assure that it is accurate and it is complete, and we know from the literature, for example, that there is underreporting of safety information in publications, and so there is a different standard that is required to be met when a company oversees a product to ensure that, once again, the data is accurate and complete.

Q So some studies are stronger than others.

A Yes.

Q You were asked last week about the number of cases you have testified in relating to Ethicon.

A Yes.

Q I think you said a handful or something, I don't remember the exact number. Fewer than ten?

A Yes.

Q Do you know how many lawsuits are actually pending in the multi-district litigation against Ethicon?

A Over 30,000 is my understanding.

Q Okay. I gather you haven't testified in 30,000 lawsuits?

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A No, I haven't.
Q Do you know -- I retained you in Ms. Ramirez's case; right?
A Yes.
Q Do you know whether your testimony is going to be used in other cases and potentially spread out among other cases? Do you know one way or another?
A I don't.
Q Has anybody suggested that to you?
A It is my understanding that may be the case, yes.
Q Okay. Just to wind this up, we have talked now for a couple days about your opinions. I started off with these questions, and I'm going to end with these questions.
Have you reached an opinion whether Ethicon violated the standard of care by failing to conduct appropriate testing to support the safe and effective use of the TVT-O -- the TVT obturator system?
A Yes.
Q What is that opinion?
A They violated the standard of care and did not do the appropriate testing.
Q Did you reach an opinion whether the labeling for the TVT obturator system was inadequate?

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A Yes, I did.
Q Due to failure to warn?
A Yes.
Q And what is that opinion?
A The labeling was inadequate.
Q Have you reached an opinion as to whether the label was false or misleading?
A Yes.
Q And what is that opinion?
A The labeling was false and misleading.
Q Did you reach an opinion as to whether Ethicon failed to meet the postmarket vigilance standard of care in management of risk?
A Yes.
Q And what is that opinion?
A Ethicon failed to meet the postmarketing vigilance standard of care.
Q And have all the opinions that you have given in your deposition been to a reasonable degree of scientific and professional certainty?
A Yes.
MR. GOSS: That's all I have.
I understand that we have got a hearing tomorrow to determine, among other things, whether this deposition is going to continue for substantially

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longer than what has gone so far. Obviously, I'm going to pass the witness at this point and I'm going to reserve my -- I'm not waiving any position that I might have in the event that Ethicon is given more time to examine the witness.
With that being said, I pass the witness.
MR. LEWIS: Ethicon and Johnson & Johnson will reserve their right to ask further questions pending the ruling from the court in the hearing that's going to take place tomorrow on the deposition.
MS. VERBEEK: We will reserve for trial.
MR. GOSS: Okay. Thank you all for your cooperation today.
THE REPORTER: Who is taking a copy? Mr. Lewis, you are taking a copy?
MR. LEWIS: That's correct. Do we have a standing order?
THE REPORTER: I believe you do. I just --
MR. LEWIS: Okay.
THE REPORTER: I probably shouldn't have asked you.
MR. LEWIS: Yeah, I'll take a copy.
THE REPORTER: And, Ms. Verbeek, are you taking a copy?
MS. VERBEEK: Yes, electronic only.
THE REPORTER: Okay. Is everybody taking a rough

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draft or nobody taking -- well, I think defense gets a rough draft, plaintiff. And, Ms. Verbeek, do you need a rough draft as well?
MS. VERBEEK: No.
THE REPORTER: And are we expediting?
MR. GOSS: Yes.
THE REPORTER: Everyone needs an expedite?
MS. VERBEEK: Yes.
MR. LEWIS: Yes.
VIDEO OPERATOR SISSON: At one o'clock, we are off the record.
(The deposition proceeding was adjourned at 1:00 P.M.)

--ooOoo--

CERTIFICATE
OF
CERTIFIED SHORTHAND REPORTER

The undersigned Certified Shorthand Reporter of the State of California does hereby certify:

That the foregoing proceeding was taken before me at the time and place therein set forth, at which time the witness was duly sworn by me;

That the testimony of the witness and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed, said transcript being a true and correct copy of my shorthand notes thereof;

That the dismantling of the original transcript will void the reporter's certificate.

In witness thereof, I have subscribed my name this date:_____.

_____
PAMELA COTTEN, CSR, RDR
Certificate No. 4497
Certified Realtime Reporter

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

ERRATA

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
PEGGY PENCE, PhD. (VOLUME II) DATE

Subscribed and sworn to before me this

_____day of_____,20___.

My commission expires:_____

_____
Notary Public